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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,373	12/29/2000	Donald L. Morton	JWCI:011:SC1	8298

7590 09/19/2005

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,373	MORTON, DONALD L.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/20/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-20 and 32-36* is/are pending in the application.

4a) Of the above claim(s) *11-17 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,18-20,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims **1, 7-10, 8-20, 32-33** are under consideration. Claims 11-17, and 34-36 are withdrawn from consideration for reasons of record, as claims are drawn to non-elected Group(s).

Response to Arguments

In view of the Appeal Brief filed on 6/20/2005, PROSECUTION IS HEREBY REOPENED. New Grounds of Rejections set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Please note any ground of rejection that has not been repeated is removed.

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 9/13/2004.

Regarding Claim 1 Applicant argues that the Examiner has not provided any bases for the rejection as to why "four common allotypes" is objectionable. Applicant argues that the term is sufficiently clear and defined, for example "common" simply refers to those allotypes that are prevalent in a given mammalian species. Applicant further asserts that they have not received any response form the office why the rejection is maintained. Applicant's argument as part of Paper filed 6/20/2005 has been considered fully, but they are not persuasive. On the last point, Office has repeatedly explained its position; selective reading of the specification and the Office Actions is not helpful. Office has repeatedly asserted that others may not consider what Applicant deems to be "common" as "common allotypes." Hence, if the boundaries of "common" are not defined, the claim is vague and indefinite. What Applicant may regard as prevalent allotypes, someone else might not. Moreover, the claim is directed to a product, and the claim fails to disclose clear boundaries that form the product. Presently, the antigen is not defined, and the MHC profile to the antigen is also not defined. Antigen is not a term interpreted in a vacuum, it must mean something in context; it has to refer to a structure that one can easily identify. Adding auxiliary language to define the antigen does not take away from the fact that the "antigen" itself has not been defined. Thus, since the antigen is not defined and the profile is not defined the claim is vague and indefinite. Thus, the claim is indefinite because the intended metes and bounds of the composition are not defined. Still further, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 112, first paragraph, for lack of written description and reasons of record advanced in the previous Office Action mailed 8/23/04. Applicant asserts that the present invention derives from the inventor's observation that person immunized with cells from other individuals appear to have an increased ability to fight off viral infections. Thus, Applicant determined that the allotypic antigens on the surface of enveloped viruses could be good targets for the host immune system, but only if that immune system was "primed" against those allotypes. Applicant further states that the invention is directed to compositions of allotypes suitable for use in preparing vaccine directed against enveloped viruses.

Additionally, Applicant argue that the wealth of information in the specification such as Figure 1-3 provides lists of HLA allotypes and their frequency of distribution by ethnic group.

Still further, Applicant asserts that the written description is satisfied because it conveys to one of skill in the art that Applicant had possession of the claimed subject matter and the Office has not meet its burden for why a person skilled in the art would not recognize in the disclosure a description of the invention is defined. Applicant concludes that a few statement by the Examiner evince no more than a complete misunderstanding of the claimed invention. Applicant's argument as part of Paper filed 6/20/2005 has been considered fully, but they are not persuasive.

First, Applicant's assertion that invention is an observation is a testament that the invention is a directed to a method rather than a product, which is what the office has argued all along, because Applicant has not disclosed any product. Moreover, Applicant admits that host

system would benefit only if it was "primed", which once again is directed to a method step, and by the way no such limitation is present in the now claimed invention (emphasis added).

Additionally, Applicant refers to Figures 1-3 as teaching and as having possession for the invention. First the Figures are not part what is claimed. Applicant understanding of his own claimed invention would be enormously helpful in advancing prosecution. The Figures refer to a list of most probable occurrence of allotypes in a given ethnic group. First, this is not the claimed invention (emphasis added). The claimed invention is directed to "a composition comprising antigens." Second, Applicant has not discovered the list of allotypes. The majority of the current disclosure is a rehash of state of the art and what was well-known in the art prior to the claimed invention regarding the MHC and its function. Applicant has failed to properly claim his invention. Consequently he blames the Office for not "understanding the wealth of information", if the wealth of information is not correctly claimed, it would have no value either to the Applicant nor to the Public at large.

Still further, Applicant is correct that they can have a generic claim, but a reasonable number of structures that encompasses the invention must be disclosed to satisfy the written description requirement. Present disclosure fails to satisfy the written description because there are no representative numbers of "antigenic composition representing at least four common allotypes" given that there is no evidence that Applicant was in possession of the broad or generic composition. Merely stating the "common allotypes" or "antigens" is not equivalent with proper written description. It seems Applicant's understanding of written description is misplaced. In order to practice the invention Applicant must have been in Possession (emphasis

added) of the claimed product at the time of invention. A wish list does not satisfy the written description. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-10, 18-20, 32, 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and disclosure (see Column 4) of U.S. Patent No. 5,840,317 A. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in 5,840,317 patent. In forming the rejection Office has determined that the same invention is being claimed twice. The same invention means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). In addition, the Office has

determined that there is no embodiment that falls within the scope of one claim, but not the other, and still further, none of claims could be literally infringed without literally infringing the other claims, i.e see claims of the ,317 patent and the pending claims. Hence, it is determined that the same invention is being claimed twice. Applicant has received patent protection for the claimed invention.

Claims 1, 7-10, 18-20, 32, 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and Column 6, lines 65-67 of U.S. Patent No. 5,882,654 A. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in 5,882,654 patent. Applicant is claiming the same invention twice. The same invention means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). In addition, the Office has determined that there is no embodiment that falls within the scope of one claim, but not the other, and still further, none of claims could be literally infringed without literally infringing the other claims

Claims 1, 7-10, 18-20, 32, 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 93, 96-100 and see Column 6, lines 6-20 of U.S. Patent No. 6,218,166 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or

claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in 5,882,654 patent. Applicant is claiming the same invention twice. The same invention means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957). In addition, the Office has determined that there is no embodiment that falls within the scope of one claim, but not the other, and still further, none of claims could be literally infringed without literally infringing the other claims

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoon et al (Ann. NY Acad. Sci., August 12, 1993, Vol. 690, pages 343-345).

Hoon et al disclosed a polyvalent melanoma cell vaccine wherein the cell comprises the same characteristic as now claimed product (see page 343, 1st full paragraph, and Figure 2). The product disclosed by the cited art is the same and/or it has the same inherent property as now claimed product. This is the same product disclosed by the Applicant's disclosure (as disclosed on page 41), and product by Hoon et al has characteristics of representing at least "four common allotypes. Claiming of a new use, new function or unknown property, which is inherently

present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bystryn (US Patent No. 5,030,621, 7/1991).

Bystryn disclosed a polyvalent vaccine wherein the composition comprised of multiple shed surface antigens from multiple human cell lines which expressed different pattern of cell surface antigens (see Column 2, lines 53-62, and Column 11, lines 40-45). The product disclosed by the cited art is the same and/or it has the same inherent property as now claimed product. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Morton et al (Ann. NY Acad. Sci., August 12, 1993, Vol. 690, pages 120-134).

As Applicant is well aware, Morton et al disclosed a polyvalent melanoma cell vaccine wherein the cell comprises the same characteristic as now claimed product (see page 120, 3rd paragraph, and page 122, 3rd full paragraph), wherein the MCV disclosed has the same profile as now claimed product. The product disclosed by the cited art is the same and/or it has the same inherent property as now claimed product. This is the same product disclosed by the Applicant in his disclosure (see page 41), which represents at least four common allotypes. The polyvalent

vaccine taught by Morton et al that has been in public use for number of years now would give the same result as now claimed product. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Still further, Applicant is directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new." This is the case here, while the Applicant may have "Observed" something interesting he certainly has not invented anything new.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bystryn et al (Ann. NY Acad. Sci., August 12, 1993, Vol. 690, pages 190-203).

The above cited art disclosed a polyvalent vaccine wherein the composition comprised of multiple shed surface antigens from multiple human cell lines which expressed different pattern of cell surface antigens including MHC class I and class II (see page 192, last full paragraph, and see the entire page 193). The vaccine MAA as defined by the cited art has the same inherent property as now claimed product, including at least four common allotypes (see page 196, last full paragraph). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459

(CCPA 1963). Still further, Applicant is directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (Cancer Immunology Immunotherapy. 1992, Vol. 34, pages 419-423).

Hayashi et al disclosed a polyvalent melanoma cell vaccine wherein the cell comprises the same characteristic as now claimed product (see the abstract, and Table 1). The product disclosed by the cited art is the same and/or it has the same inherent property as now claimed product. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schirrmacher V. (Onkologie, 1993, Vol. 16, No. 5, pages 290-296).

Schirrmacher taught an active specific immunotherapy (ASI) as a polyvalent cell vaccine (see the abstract). Schirrmacher's vaccines comprised of freshly isolated autologous intact tumor cells from cancer patients were mixed and inactivated (see page 294, left column, last paragraph). It can be reasonably inferred that because the tumor cells came from different

patients it comprises of at least four common allotypes. The product disclosed by the above cited art has the same inherent property as now claimed product. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Still further, Applicant is directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.

Claims 1, 7-10, 18-20, 32, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bystryn et al (Journal of Biological Response Modifiers, June 1986, Vol. 5, No. 3, pages 211-224).

The above cited art disclosed a polyvalent vaccine wherein the composition comprised of multiple shed surface antigens from multiple human cell lines which expressed different pattern of cell surface antigens (see page 212, 3rd full paragraph, page 216-217). The product MAA disclosed by the cited art has the same inherent property as now claimed product. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
9/14/2005

ALI R. SALIMI
PRIMARY EXAMINER